

### REMARKS

The pending Office Action addresses claims 21-36, rejecting all the claims. By this response, Applicant amends independent claims 21 and 33 to further highlight the non-linear propagation of ultrasound energy being claimed. Specifically, claim 21 is amended to recite the step of introducing an amount of ultrasound energy *at sufficiently high pressure amplitudes to propagate the ultrasound energy non-linearly* into a dermis layer of the target area. Claim 33 is amended to recite a control device constructed and arranged to control the transducer and induce ultrasound energy *at sufficiently high pressure amplitudes so as to cause non-linear propagation of the energy* into the dermis layer sufficient to induce new connective tissue formation. Support for these limitations can be found at page 3, line 9-18 of the specification. Accordingly, no new matter is added by these amendments.

In view of the amendments and remarks below, Applicants respectfully request reconsideration of the application.

#### ***Information Disclosure Statement***

As requested by the Examiner on page 2 of the Office Action, Applicant provides a copy of the Information Disclosure Statement entered on May 7, 2002 along with this response.

#### ***Double Patenting Rejections***

The Examiner rejects claims 21-36 under an obviousness-type double patenting rejection as being unpatentable over claims 1-41 of U.S. Patent No. 6,325,769. The Examiner also rejects claims 21-36 under an obviousness-type double patenting rejection as being unpatentable over claims 1-18 of U.S. Patent No. 6,113,559. Applicant will file a timely terminal disclaimer to overcome these rejections, once the Examiner indicates that claims 21-36 are allowable.

#### ***Prior Art Rejections***

The Examiner rejects claims 21-24, 27-29 and 31-35 under 35 U.S.C. §102(e) as being anticipated by Knowlton (U.S. Patent No. 6,387,380). Claims 25 and 26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Knowlton, in view of Hutchinson et al. (U.S. Patent

No. 6,135,971), while claims 30 and 36 are rejected as being unpatentable over Knowlton, in view of Lele (U.S. Patent No. 4,938,217). For all of the following reasons, Applicant respectfully disagrees and requests withdrawal of all the prior art rejections.

Each of the Examiner's rejections relies solely, or in part, on the Knowlton reference. However, the Knowlton reference does not anticipate, nor substantially disclose, the claimed invention. Knowlton discloses an apparatus for applying radiant energy through the skin to selectively kill fat cells and partially denaturize the collagen tissue layer of skin, allowing the collagen to tighten and thereby sculpt or contour the skin. As correctly pointed out by the Examiner, Knowlton describes on col. 4, lines 42-44 that ultrasound energy is a suitable type of radiant energy for his invention. But Knowlton falls short of disclosing or suggesting that the ultrasound energy, or any of the other types of radiant energy for that matter, can propagate in a *non-linear* fashion through dermal tissue, as is required of the claimed invention.

Independent claim 21 requires the step of introducing an amount of ultrasound energy *at sufficiently high pressure amplitudes to propagate the ultrasound energy non-linearly* into a dermis layer of the target area. Likewise, claim 33 requires a control device constructed and arranged to control the transducer and induce ultrasound energy *at sufficiently high pressure amplitudes so as to cause non-linear propagation of the energy* into the dermis layer sufficient to induce new connective tissue formation. None of these limitations are found in the Knowlton reference. While ultrasound energy is mentioned as a suitable energy type, no specific parameters for its application are disclosed. Rather, most of the Knowlton specification is directed to the use of radiant heat sources for effecting denaturation of collagen molecules within the skin and controlling such energy application through temperature regulation (*see*, col. 7, lines 17-24 and col. 8, lines 47-67).

As described in Applicant's specification at page 3, lines 9-18, ultrasound energy is applied at sufficiently high pressure amplitudes to introduce non-linearity (i.e., the speed of propagation of the energy pulses through the target region of skin will be higher than the normal speed of sound propagation through skin.) Typically, the non-linear behavior will be exhibited where the acoustic pulses have an intensity within the target region of about 500 to about 1000 watts/cm<sup>2</sup>, at a duration ranging from about 10 nanoseconds to about 200 microseconds.

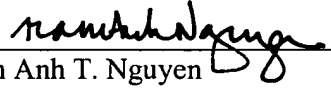
Because Knowlton fails to disclose the propagation of ultrasound energy in a non-linear fashion, as required of the claims, the reference cannot be said to anticipate the claimed invention. The Examiner is therefore requested to remove the anticipatory rejection of claims 21-36 over Knowlton.

Because Knowlton fails to substantially disclose the claimed invention for the reasons stated above, its deficiencies would not be overcome by its combination with either Hutchinson or Lele. This is because Knowlton fails to disclose the step of introducing an amount of ultrasound energy *at sufficiently high pressure amplitudes to propagate the ultrasound energy non-linearly* into a dermis layer of the target area, or a control device constructed and arranged to control the transducer and induce ultrasound energy *at sufficiently high pressure amplitudes so as to cause non-linear propagation of the energy* into the dermis layer sufficient to induce new connective tissue formation. For these reasons, Knowlton fails to substantially disclose each and every limitation of the claimed invention. And since neither Hutchinson or Lele teach or suggest a non-linear propagation of ultrasound energy into a target region of skin, their combination with Knowlton would not overcome the setbacks in the Knowlton reference.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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